

MAR 30 2012

80 Oakland Street
Watertown, MA 02472
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510(k) Summary

January 17, 2012

Kenneth J. Berk
80 Oakland Street
PO Box 780
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Telephone: 617-926-6666
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Email: Pulpdent@pulpdent.com

DEVICE NAME: *PULPDENT ETCH-RITE™ SUPREME*
CLASSIFICATION NAME: Resin tooth bonding agent
FDA PRODUCT CODE: KLE, CFR 872.3200

PREDICATE DEVICES: Pulpdent *Etch-Rite™* 38% Phosphoric Acid Etching Gel
Pulpdent *Etch Royale™* 37% Phosphoric Acid Etching Gel

DESCRIPTION:

Pulpdent Etch-Rite Supreme is a 36% phosphoric acid etchant in a soft gel that does not dry out quickly, that flows through small applicator tips and that washes off readily. *Etch-Rite Supreme* is colored dark purple for contrast with tooth enamel and easy visualization.

INTENDED USE

Pulpdent Etch-Rite Supreme is used by the dental professional for etching dentin, enamel or glass ionomers as one step in tooth restoration.

COMPARISON WITH PREDICATE PRODUCTS:

Pulpdent Etch-Rite Supreme is substantially equivalent in design, composition and intended use to the predicate products that have been given 510(k) Premarket approval as Class II Dental Devices under CFR 872.3200.

	Pulpdent Etch-Rite Supreme	Pulpdent Etch-Rite K882576	Pulpdent Etch Royale K031915
Chemical Composition:	36% Phosphoric Acid Silica gel Propylene glycol	38% Phosphoric Acid Silica gel	37% Phosphoric Acid Glycerin Silica Gel
Consistency	Soft gel	Thixotropic gel	Soft gel
Applicator tip	25 gauge, pre-bent	25 gauge, pre-bent	25 gauge, pre-bent
Color	Dark purple	Blue	Dark blue
Intended Use	Etch dentin, enamel and glass ionomer cements	Etch dentin, enamel and glass ionomer cements	Etch dentin and tooth enamel.

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Summary of Performance Testing – Bench

The following test results demonstrate that *Etch Supreme* performs as intended:

Specific gravity	1.280
Solubility in water	100 %
pH	1.0
Appearance and odor	Dark purple gel with mild, characteristic odor
Shelf-Life	Two years

CONCLUSION:

From the above comparisons, the bench testing, a search of the relevant scientific literature and the organizational experience with the Etch-Rite line of etchants, it can be concluded that *Etch-Rite Supreme* is substantially equivalent in design, composition, performance and intended use to the predicate products. General usage of Etch-Rite for more than 20 years and Etch Royale for over 10 indicates a high benefit-to-risk ratio.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Mr. Kenneth J. Berk
Director of Research
Pulpdent Corporation
80 Oakland Street
Watertown, MA 02472

MAR 30 2012

Re: K120213
Trade/Device Name: Pulpdent Etch-Rite™ Supreme
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Codes: KLE
Dated: January 17, 2012
Received: January 24, 2012

Dear Mr. Berk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Page 2 – Mr. Berk:

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


 Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120213

Device Name: *Pulpdent Etch-Rite™ Supreme*

Indications For Use:

Pulpdent Etch-Rite Supreme is a 36% phosphoric acid etchant in gel form that is used by the dental professional for etching dentin, enamel or glass ionomers as one step in tooth restoration.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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